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EXAMINER

ROBINSON, BINTA M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/019,355

Applicant(s)

BLACKLER ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

### **Detailed Action**

The 112, second paragraph rejections of claims 15, 16 and 18 are withdrawn in light of applicant's comments in the paper filed 4/23/04. Claims 13-14 and 17-23 are not allowable as stated at paper no. 12.

### **(new rejections and objections)**

#### ***Claim Objections***

Claim(s) 24 and 25 is/are objected to for being substantial duplicates of claim 1. Claim 25 is objected to for being substantial duplicates of claim 24. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k). This objection can be overcome by deleting claim 25.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses that the instant compounds are made according to methods described in EP 0306228 and WO 9405659. However, different polymorphic

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forms of the salts of compound, 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione have also been disclosed as having been made by the same methods as described in EP 0306228 and WO 9405659. However, different polymorphs can not be produced by the same method. It is impossible to synthesize more than one metastable polymorphic form using the same method to synthesize the different forms. At a given temperature and pressure, only one polymorph can be produced.

There is also a lack of description as to whether the pharmaceutical carriers are able to maintain the compound in the hydrate forms claimed. Substances may hydrate/dehydrate in response to changes in environmental conditions. (See page 126 of Brittain). Processing a compound into a pharmaceutical composition could dehydrate or create a different hydrate than the hydrates being claimed. (See page 126 of Brittain). Changes in hydration state can result in variable potencies depending on handling conditions during weighing steps, the kinetics of the hydration/dehydration process, and the environmental conditions during processing. (See page 127, Brittain).

There is also no description in the specification of the pharmaceutical compositions claimed in terms of their x-ray diffraction pattern or infrared spectrum data being claimed. The X-Ray Diffraction and Infrared Spectrum data on pages 7-8 of the specification is only pertaining to compounds rather than the compositions being claimed. Based on the unpredictability in the art, the applicant is not entitled to the X-ray diffraction patterns and infrared spectra claimed for the pharmaceutical compositions being claimed.

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There is also no description as to how the applicant produced and isolated the particular dihydrate being claimed. Claim 18 is inoperable, because this dihydrate can not be obtained simply by treating the compound with HCL counterion and water. Only when water is incorporated into the crystal lattice of the compound in stoichiometric proportions, are particular hydrates formed. (See page 202, Brittain). Applicant would have to show how the particular dihydrate in claim 18 was isolated.

Based on prior art of record which is Chemical & Engineering News (February 24, 2003, "The Right Stuff" by A. Maureen Roui, page 32, it was clearly disclosed that formulation of drugs or pharmaceuticals in its metastable forms, for example, one polymorph, is highly unpredictable. The meta stable forms will disappear and change into the most thermodynamically stable form. The specification lacks description of how the pharmaceutical composition can be prepared in order to maintain the particular compound of a particular form with the particular infrared spectra and X- ray diffraction being claimed. Disclosure of X-ray diffraction patterns for pharmaceutical compositions comprising the polymorph forms are lacking in the specification. The X-ray diffraction patterns and infrared spectra on pages 7-8 and the referenced Figure I only supports the polymorphic forms of the compounds not the pharmaceutical compositions. The specification has also not described how the polymorph forms being claimed will be maintained and prevented from converting to other forms when they are used in a method for treating diabetes mellitus or other conditions associated with it in claims 22-23.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Fouche* 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

***The nature of the invention***

The nature of the invention is the preparation of novel polymorphic forms of 5-[4[[2-(N-pyridyl)amino]ethoxy]benzyl]thiazolidine-2,4-dione and the use of these forms as pharmaceutical compositions for treatment of diabetes mellitus and conditions associated with this condition.

**State of the Prior Art**

Polymorphs arise when molecules of a compound stack in the solid state in distinct ways. (See Chemical Engineering News, page 32). Although identical in chemical composition, polymorphs can have very different properties. They are distinguishable by various analytical techniques, especially X-ray power diffraction. Additionally, solids may form hydrates. Polymorphs tend to convert from less stable to more stable Forms. (See Chemical Engineering News, page 32). No method exists to predict the polymorphs of a solid compound with any significant certainty. In Drug design, it is best to work with the most stable polymorph, because it will not convert any further, however, the most stable polymorph usually is the least soluble. To improve bioavailability, drug companies sometimes trade off polymorph stability with solubility, choosing to work instead with the less stable forms first, also known as the metastable forms. Polymorphs can convert from one form to another during the manufacturing process of a pharmaceutical drug. See (Chemical Engineering News), page 33, which will can change the pharmacological effects of the drug. This is why it is important for to monitor the polymorph during manufacture of the drug to see if it persists during manufacture.

***The amount of direction or guidance present and the presence or absence of working examples***

Figure I and pages 7-8 of the specification only disclose the X-ray diffraction pattern and infrared spectra of compounds of particular forms rather than the compositions being claimed in terms of the specific X-ray diffraction patterns being claimed. Polymorphs often change into other polymorph forms during drug manufacture (See Chemical Engineering News) into a

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pharmaceutical composition. Based on the unpredictability in the art, the applicant is not entitled to the X-ray diffraction patterns claimed for the pharmaceutical compositions being claimed.

### **The breadth of the claims**

The breadth of the claims are the pharmaceutical compositions claimed in claims 20-22 in addition to the specific polymorph form claimed with the specific X-ray diffraction and infrared spectra claimed in claims 13-19, in addition to a method of treating diabetes mellitus and all conditions associated with diabetes mellitus with all polymorph and nonpolymorph forms of, 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione in claims 22-25.

### ***The quantity of experimentation needed***

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the pharmaceutical compositions being claimed and verifying that they have the specific X-ray diffraction patterns being claimed which are not disclosed in the specification.

In terms of the 8<sup>th</sup> Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:



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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 21, 22, 23, 24, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et. al. (WO 98/57634). Smith et. al. teaches the instant method of treating diabetes mellitus and Type II diabetes mellitus in a mammal with 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione as well as a pharmaceutical composition containing 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and tablets and capsules containing 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione. At page 12, see claims 4-10. The Smith method of treating diabetes mellitus and Type II diabetes mellitus in a mammal with 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione as well as Smith pharmaceutical composition containing 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and tablets and capsules containing 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione is identical to the instant method, as well as a pharmaceutical composition containing 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and tablets and capsules containing 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione since at physiological conditions, the instant compound is identical to the Smith compound, unless there is a showing of unobvious difference. Hence the instant method of treating with the instant compound, and the pharmaceutical compositions, tablets and capsules containing the instant compound are identical to the instant method of treating, pharmaceutical compositions, tablets and capsules containing the Smith compound.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 21, 22, 23, 24, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et. al (WO 97400177, See CA 128:3688) in further view of Patani.

Andersen teaches a pharmaceutical composition comprising compound, 2, 4-Thiazolidinedione, 5-[difluoro[4-[2-[(5-methyl-2-pyridinyl)amino]ethoxy]phenyl]methyl]. CA 128:3688, see the pharmaceutical composition. The difference between the prior art composition and the instantly claimed pharmaceutical composition is the substitution on the pyridinyl moiety and on the methylene moiety of the compound in the pharmaceutical composition. In the instant pharmaceutical composition containing the instant compound, there are no substituents on the pyridyl ring or the methylene moieties of the compound. In the prior art composition containing the instant compound, the methylene moiety is disubstituted with fluorine and the pyridyl moiety is substituted with methyl. The prior art compound and the instant compound are bioisosteres of each other. Bioisosteres are compounds that differ by an atom or moieties that share similar physiochemical properties and consequently two compounds that are bioisosteres of one another have similar biological activity, which may even be

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antagonistic. Methyl and fluorine are bioisostere replacements for hydrogen (See Patani et. Al.)

It would have been obvious to one of ordinary skill in the art to synthesize bioisosteres of this class of compounds and pharmaceutical compositions containing them. Accordingly, the pharmaceutical composition containing the instant compound is deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed composition over those of the prior art composition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 17, line 1, page 5 of the amendment filed 4/23/04, the term "isolated" is indefinite. It is ambiguous as to how isolated the compound is and how this term further limits claim 13, since the dihydrate in claim 13 had to have been isolated as well.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10030877 (WO 00/64893). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 10 of the copending case is claiming a pharmaceutical composition of a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione. The copending Application No. 10030877 anticipates the instant pharmaceutical compositions since at physiological conditions, the 10030877 (WO 00/64893) compound in the pharmaceutical composition is identical to the instant compound in the instant composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10 and 14 of copending Application No. 10048123 (WO 00/64896). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 10 and 14 of the copending case is claiming a pharmaceutical composition of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino]ethoxy]benzyl]thiazolidine-2,4-dione and a method for treating diabetes mellitus. The copending Application No. 10048123 anticipates the instant pharmaceutical compositions and the method of treating diabetes mellitus with these compositions since at physiological conditions, the 10048123 compound in the pharmaceutical composition is identical to the instant compound in the instant composition and hence the 10048123 method of treating diabetes mellitus is identical to the instant method of treating diabetes mellitus with the instant compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10 and 14 of copending Application No. 10703887 (WO 00/64892). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 10 and 14 of the copending case are claiming a pharmaceutical composition of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and a method for treating diabetes mellitus. The copending Application No. 10030877 anticipates the instant pharmaceutical compositions containing the instant maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and the method of treating diabetes mellitus with this compound since at physiological conditions, the instant compound is identical to the 10703887 compound and hence a method of treating diabetes mellitus with this compound and a pharmaceutical composition containing this compound are identical to the 10030877 pharmaceutical composition and method of treating diabetes mellitus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 1003087, (WO 0063206). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because claims 12 of the copending case is claiming a method for treating diabetes mellitus with a hydrochloride dihydrate of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione. The copending Application No. 1003087 anticipates the instant method for treating diabetes mellitus with a hydrochloride dihydrate of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione since at physiological conditions, the instant compound is identical to the 10703887 compound and hence the instant method of treating diabetes mellitus with the instant compound is identical to the 1003087 method of treating diabetes mellitus with a hydrochloride dihydrate of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione.

. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 and 16 of copending Application No. 10082879 (US2002137940). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are claiming a pharmaceutical composition of a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and a method for treating diabetes mellitus with this hydrate. The copending Application No. 10082879 anticipates the instant pharmaceutical compositions and the method of treating diabetes mellitus with these compounds since at physiological conditions, the instant compound is identical to the 10082879 compound and hence the instant method of treating diabetes mellitus with the instant compound and the pharmaceutical composition containing the instant compound is identical to the 10082879 method of treating diabetes mellitus with a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and pharmaceutical composition containing a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione.



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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13 of U.S. Patent No. 664278.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims are claiming a pharmaceutical composition of a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and a method for treating diabetes mellitus with this hydrate. The US Patent 664278 anticipates the instant pharmaceutical compositions and the method of treating diabetes

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mellitus with these compositions since at physiological conditions, the instant compound is identical to the U.S. Patent No. 664278 compound and hence the instant method of treating diabetes mellitus with the instant compound and a pharmaceutical composition containing the instant compound are identical to the U.S. Patent No. 664278 method of treating diabetes mellitus with a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and the 664278 pharmaceutical composition containing this compound.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 and 16 of copending Application No. 10321055 (US2003/0120078 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because although the conflicting claims are not identical, they are not patentably distinct from each other because claims are claiming a pharmaceutical composition of a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and a

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method for treating diabetes mellitus with this hydrate. The copending Application No. 10321055 anticipates the instant pharmaceutical compositions and the method of treating diabetes mellitus with these compositions since at physiological conditions the instant compound is identical to the compound and hence the instant pharmaceutical composition containing said compound and the instant method of treating diabetes mellitus with the instant compound is identical to the 10321055 method of treating diabetes mellitus with a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione and a 10321055 pharmaceutical composition containing a hydrate of a maleic acid salt of 5-[4[[2-(N-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699.


A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

A handwritten signature in black ink, appearing to be 'BMR', is written over the printed name.

BMR

  
JOSEPH K. MCKANE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600